



Dartmouth-Hitchcock Medical Center

James P. AuBuchon, MD
Professor of Pathology and Medicine
Medical Director, Blood Bank and Transfusion Service
Chair, Residency Committee

1476 *99 SEP 8 10:18
Department of Pathology
One Medical Center Drive
Lebanon, New Hampshire 03756
(603) 650-7171
Fax: (603) 650-4845

September 2, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 99D-2213
Guidance for Industry: Revised Recommendations for the Invalidation of Test
Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to
Test Donors

Dear Sirs:

I am writing to object strongly to one of the provisions of this draft guidance.

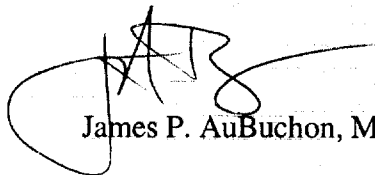
The utility of using external ("run") controls in laboratory testing is well understood by clinical pathologists. Their application to infectious disease testing is entirely appropriate.

However, their interpretation and the actions taken based on their results should follow commonly accepted principles and scientific logic. In particular, Section III.C. is an illogical extension of the concept of run controls. If one or more run controls are not within their specified ranges, the entire run should be invalidated. Accepting the reactive results as valid but requiring the repetition of non-reactive results flies in the face of scientific logic. If a sample is truly reactive, it will prove this in a subsequent valid ("in-control") run. Discarding all results of a run that does not meet these specifications will in no way jeopardize the safety of transfusion recipients.

Therefore, I strongly urge that the FDA adopt widely accepted principles and practices of run controls as practiced throughout clinical pathology for infectious disease marker testing of donors.

Thank you.

Sincerely,


James P. AuBuchon, MD

99D-2213

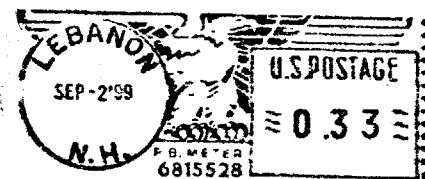
C1



Dartmouth-Hitchcock Medical Center

One Medical Center Drive
Lebanon, New Hampshire 03756

2523



DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 106/
ROCKVILLE, MD 20852

DOCKET No. 99D-2213

20837/0001

